DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 2, 2015

Sejoy Electronics & Instruments Co., Ltd.
Ren Yunhua
General Manager
Bldg 2, No. 202, Zhenzhong Rd
West Lake Economy & Technology Zone
Hangzhou, Zhejiang 310030 CN

Re: K150545
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor (BP-1305, BP-1307, BP-1326, BP-1318, BP-1319, BP-1211, BP-1312, BSP-11, BSP-12, BSP-13)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 15, 2014
Received: March 3, 2015

Dear Ren Yunhua:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

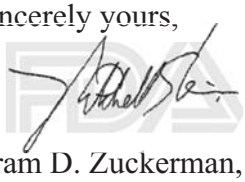
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

世佳电子有限公司
Sejoy Electronics & Instruments Co., Ltd.

Indications for Use

510(k) Number (if known):

Device Name: Blood Pressure Monitors for BP-1211，BP-1312，BP-1305，BP-1307，BP-1318，BP-1319，BP-1326，BSP-11，BSP-12，BSP-13

Indications For Use:

Measure blood pressure (systolic and diastolic) and pulse rate.

Prescription Use	**AND/OR**	**Over-The-Counter Use √**
(Part 21 CFR 801 Subpart D)		**(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

世佳电子有限公司
Sejoy Electronics & Instruments Co., Ltd.

510(k) Summary

The assigned 510(k) number is:_____

1. Date Prepared:

2014.12.15

2. Submitter's Identification:

Name: Sejoy Electronics & Instruments Co., Ltd.
Add.: Building 2, No.202, Zhenzhong Road, West Lake Economy & Technology Zone, Hangzhou, China 310030
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3. Name of the Device:

Trade Name: Fully Automatic Digital Blood Pressure Monitor
Including the following models:
- BP-1211，BP-1312，BP-1305，BP-1307，BP-1318，BP-1319，BP-1326，BSP-11，BSP-12，BSP-13 for Arm-type Fully Automatic Digital Blood Pressure Monitor

Common Name: Blood Pressure Monitor
Classification name: Non-invasive blood pressure measurement System
21 CFR 870-1130, Class II, 74-DXN.

4. Classification Information:

Regulation Number: 870.1130
Product Code: DXN
Device Class: II
Panel: 74 Cardiovascular

5. Predicate Device Information:

The Arm-type Fully Automatic Digital Blood Pressure Monitors are substantially equivalent to the following device: Blood Pressure Monitor (Model **BP-1307)**； FDA 510(k) number: K120554 ； manufactured by SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

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6. Device Description:

The arm-type uses an inflatable cuff which is wrapped around the patient's upper arm. The cuff is inflated automatically by an internal pump in the device. The systolic and diastolic blood pressures are determined by oscillometric method and silicon integrate pressure sensor technology. The deflation rate is controlled by a preset mechanical valve at a constant rate. The pressure of the cuff is completely released automatically at the end of the measurement. At the same time, the measurements are displayed on the LCD display for three minute. There is a maximum pressure safety setting at 300 mmHg. The device will not inflate the cuff higher than 300 mmHg. For BP-1305, BP-1307,BP-1211，BP-1312，BP-1318，BP-1319，BP-1326，BSP-11，BSP-12，BSP-13, the blood pressure results are compared with WHO (World Health Organization) Blood Pressure classification, which are severe Hypertension, Moderate Hypertension, Mild Hypertension, High-normal, Normal, and Optimal. The corresponding LCD segment will be turned on along with the systolic, diastolic, and pulse rate information. BP-1305, BP-1307,BP-1312，BP-1318，BP-1319，BP-1326，BSP-11，BSP-12，BSP-13will display an irregular heartbeat symbol " " if an irregular heartbeat was detected during the measurement process. BP-1305,BP-1312，BP-1318，BP-1319，BP-1326，BSP-11，BSP-12，BSP-13 can display average results in three ways: BP-1307 can display the average of all measurements, the average of all AM (5:00 AM-8:59AM) measurements, and the average of all PM (18:00 PM-19:59 PM) measurements.

The detail comparisons among devices are listed below:

Features / Models	A	B	C	D	E	F	G	H	I（mm）	J	K(mm)	L	M	N
BP-1307 (The Predicate Devices)	●	●	120 Memories in two groups	●	○	●	●	●	166×114×72	22-36cm	84.1×55.1	●	○	○
BP-1211	●	●	120 Memories in one groups	●	○	●	○	○	131×102×65	22-36cm	45×30	○	○	○
BP-1312	●	●	120 Memories in two groups	●	○	●	●	●	131 ×102 ×65	22-36cm	62.4×46.1	○	○	○
BP-1318	●	●	120 Memories in two groups	●	○	●	●	●	139× 88× 43	22-36cm	66 ×43	○	○	○
BP-1326	●	●	120 Memories in two groups	●	○	●	●	●	139 ×88 ×44	22-36cm	65.9×42.8	○	○	○
BP-1305	●	●	120 Memories in two groups	●	○	●	●	●	166 ×114× 72	22-36cm	84.1×55.1	○	O	O
BP-1307	●	●	120 Memories in two groups	●	●	●	○	●	166 ×114× 72	22-36cm	102.1×68.9	O	O	O
BP-1319	●	●	120 Memories in two groups	●	○	●	●	●	166 ×114× 72	22-36cm	101.6×67.6	O	O	O
BSP-11	●	●	120 Memories in one groups	●	○	●	●	●	140 ×98× 48	22-36cm	62.3× 46	○	○	○
BSP-12	●	●	120 Memories	●	○	●	●	●	148× 100× 56	22-36cm	84.1×55.1	O	O	O

			in two groups											
BSP-13	●	●	120 Memories in two groups	●	○	●	●	●	164× 111× 60	22-36cm	102.1×68.9	O	O	O

A = Powered by 4 AA size batteries
B= Powered by AC adaptor
C = Memory Size
D = Time & Date
E = Results Average in Three way
F = WHO (World Health Organization) Classification Indicator
G = Last 3 Results Average
H = Irregular Heartbeat Detection
I = Outside Demission (L x W x H in mm)
J = Cuff Size
K = LCD Size (Viewing Area in mm)
L = LCD Backlight
M= Voice
N= PC connecter
● = Yes
○ = No
O= Optional function depending on clients' needs

The devices are all designed and manufactured according to AAMI / ANSI / IEC 80601-2-30:2009, medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

7. Intended Use:

The Fully Automatic Blood Pressure Monitors BP series and BSP series are intended for used by adults with 12 years and older to measure the systolic and diastolic blood pressure and pulse rate.

The intended user and the indication for use of the Fully Automatic Blood Pressure Monitors

BP series and BSP series as described in the labeling are nearly the same as their Predicate devices, Blood Pressure Monitor (Model: BP-1307).

8. Summary comparing technological characteristics with predicate device:

Technological Characteristics	**Comparison result**
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Identical
Biocompatibility	Identical
Mechanical Safety	Identical

Energy Source	Identical
Standards Met	Identical
Electrical Safety	Identical
EMC	Identical
Function	Similar

The difference of technological characteristic between the predicate device and the submit arm-type fully automatic blood pressure monitors is the appearance and the function.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards including IEC 80601-2-30:2009, medical electrical equipment - part 2-30 as well as AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, a2:2010/(r)2012 ， IEC/EN 60601-1-2:2007, ISO 10993-5: 2009 Biological evaluation of medical devices —Part 5:Tests for in vitro cytotoxicity and ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.

Guidance documents include the “FDA Non-invasive Blood Pressure (NIBP) Monitor Guidance” and “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and “FDA Bluebook Memorandum G95-1Use of International
Standard ISO 10993.”

Non-clinical Tests:

Electromagnetic Compatibility Test according to IEC/EN 60601-1-2:2007

General Safety Provisions Test according to AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, a2:2010/(r)2012

Performance Test according to IEC 80601-2-30:2009, medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers The test result all meet or exceed the requirement of the standards.

Biocompatibility Test according to FDA Bluebook Memorandum G95-1Use of International Standard ISO 10993, ISO 10993-5: 2009 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity and ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.

10. Discussion of Clinical Tests Performed:

Clinical tests were performed and complied the accuracy requirements of ISO 81060-2 Second edition 2013-05-01, non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type.

11. Conclusions:

Our Arm-type Fully Automatic Blood Pressure Monitors BP-1211，BP-1312，BP-1305，BP-1307，BP-1318，BP-1319，BP-1326，BSP-11，BSP-12，BSP-13 have the same intended use and similar technological characteristics as the Blood Pressure Monitor (Model BP-1307)；FDA 510(k) number: K120554;manufactured by SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared devices.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device, and the new models as mentioned on this submission are considered substantial equivalent to the predicate devices.